

or a specific method's results demonstrate bias that is not observed with actual patient specimens, as determined by a defensible scientific protocol, a comparative method or a method group ("peer" group) may be used. If the method group is less than 10 participants, "target value" means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

*Unsatisfactory proficiency testing performance* means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

*Unsuccessful participation in proficiency testing* means any of the following:

(1) Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events.

(2) Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.

(3) An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive or two out of three testing events.

(4) Failure of a laboratory performing gynecologic cytology to meet the standard at § 493.855.

*Unsuccessful proficiency testing performance* means a failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

*Validation review period* means the one year time period during which HCFA conducts validation inspections and evaluates the results of the most recent surveys performed by an accreditation organization or State laboratory program.

[57 FR 7139, Feb. 28, 1992, as amended at 57 FR 7236, Feb. 28, 1992; 57 FR 34013, July 31, 1992; 57 FR 35761, Aug. 11, 1992; 58 FR 5220, Jan. 19, 1993; 58 FR 48323, Sept. 15, 1993; 60 FR 20043, Apr. 24, 1995; 63 FR 26732, May 14, 1998]

### § 493.3 Applicability.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it—

(1) Has a current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or

(2) Is CLIA-exempt.

(b) *Exception.* These rules do not apply to components or functions of—

(1) Any facility or component of a facility that only performs testing for forensic purposes;

(2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients; or

(3) Laboratories certified by the National Institutes on Drug Abuse (NIDA), in which drug testing is performed which meets NIDA guidelines and regulations. However, all other testing conducted by a NIDA-certified laboratory is subject to this rule.

(c) *Federal laboratories.* Laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993; 60 FR 20043, Apr. 24, 1995]

### § 493.5 Categories of tests by complexity.

(a) Laboratory tests are categorized as one of the following:

(1) Waived tests.

(2) Tests of moderate complexity, including the subcategory of PPM procedures.

(3) Tests of high complexity.

(b) A laboratory may perform only waived tests, only tests of moderate complexity, only PPM procedures, only tests of high complexity or any combination of these tests.

## § 493.15

(c) Each laboratory must be either CLIA-exempt or possess one of the following CLIA certificates, as defined in § 493.2:

- (1) Certificate of registration or registration certificate.
- (2) Certificate of waiver.
- (3) Certificate for PPM procedures.
- (4) Certificate of compliance.
- (5) Certificate of accreditation.

[60 FR 20043, Apr. 24, 1995]

### § 493.15 Laboratories performing waived tests.

(a) *Requirement.* Tests for certificate of waiver must meet the descriptive criteria specified in paragraph (b) of this section.

(b) *Criteria.* Test systems are simple laboratory examinations and procedures which—

- (1) Are cleared by FDA for home use;
- (2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
- (3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

(c) *Certificate of waiver tests.* A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others:

(1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following:

- (i) Bilirubin;
- (ii) Glucose;
- (iii) Hemoglobin;
- (iv) Ketone;
- (v) Leukocytes;
- (vi) Nitrite;
- (vii) pH;
- (viii) Protein;
- (ix) Specific gravity; and
- (x) Urobilinogen.

(2) Fecal occult blood;

(3) Ovulation tests—visual color comparison tests for human luteinizing hormone;

(4) Urine pregnancy tests—visual color comparison tests;

(5) Erythrocyte sedimentation rate—non-automated;

## 42 CFR Ch. IV (10–1–99 Edition)

(6) Hemoglobin—copper sulfate—non-automated;

(7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use;

(8) Spun microhematocrit; and

(9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

(d) *Revisions to criteria for test categorization and the list of waived tests.* HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the FEDERAL REGISTER in a notice with opportunity for comment.

(e) Laboratories eligible for a certificate of waiver must—

(1) Follow manufacturers' instructions for performing the test; and

(2) Meet the requirements in subpart B, Certificate of Waiver, of this part.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993]

### § 493.17 Test categorization.

(a) *Categorization by criteria.* Notices will be published in the FEDERAL REGISTER which list each specific test system, assay, and examination categorized by complexity. Using the seven criteria specified in this paragraph for categorizing tests of moderate or high complexity, each specific laboratory test system, assay, and examination will be graded for level of complexity by assigning scores of 1, 2, or 3 within each criteria. The score of "1" indicates the lowest level of complexity, and the score of "3" indicates the highest level. These scores will be totaled. Test systems, assays or examinations receiving scores of 12 or less will be categorized as moderate complexity, while those receiving scores above 12 will be categorized as high complexity.

NOTE: A score of "2" will be assigned to a criteria heading when the characteristics for a particular test are intermediate between the descriptions listed for scores of "1" and "3."

(1) *Knowledge.*